

## REMARKS

By the present Amendment, claims 1-11 are cancelled and claims 12-26 are added. This leaves claims 12-26 pending in the application, with claims 12 and 24 being independent.

### Substitute Specification

The specification is revised to avoid the objections raised in the Office Action and to eliminate grammatical and idiomatic errors in the originally presented specification. The number and nature of the changes made in the specification would render it difficult to consider the case and to arrange the papers for printing or copying. Thus, the substitute specification will facilitate processing of the application. The substitute specification includes no “new matter”. Pursuant to M.P.E.P. § 608.01(q), voluntarily filed, substitute specifications under these circumstances should normally be accepted. A marked-up copy of the original specification is appended hereto.

### Rejections Under 35 U.S.C. § 112, Second Paragraph

Original claims 2, 3 and 9-11 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. By the present Amendment, the originally filed claims have been rewritten to avoid the language alleged to be indefinite in the Office Action. All language of the presently pending claims is now believed to be clear and definite.

Thus, the pending claims are definite and comply with 35 U.S.C. § 112.

### Rejection Under 35 U.S.C. §§102 and 103

Claim 12 covers a method of producing and filling containers. The method comprises the steps of extruding a tube 12 of softened plastic material into an open mold 16, closing the tube at its a projecting end by closing the mold to form a container bottom, separating the tube above the

mold by a separating element 28 to form a filler opening, moving the mold with the tube having the filler opening into mold into a filling position (Fig. 1c), after the tube is formed into the container by generating a pressure gradient acting on the tube in the mold to expand the tube, filling the container through the filler opening, sealing the filler opening, covering the filler opening by a sterile barrier 30 at least from the formation time for the filler opening to filling of the tube, and conveying at least one sterile medium in a direction of the filler opening from the sterile barrier by a media delivery device.

Claim 24 covers a device for producing and filling containers. The device comprises at least one mold 16 having mold parts 14 movable between open and closed positions. An extruder 10 extrudes at least one tube 12 of softened plastic material into the mold with the mold parts in their open positions. Welding edges on the mold weld a projecting end of the tube to form a container bottom. A pressure gradient generator acts on and expands the tube in the mold. A separating element 28 forms a filler opening by separating the tube, and is movable above the mold between a retracted position and an operating position. A filling device 22 is located in a sterile filling space. A displacement device moves the mold between an extrusion position below the extruder (Fig. 1a) and a filling position (Fig. 1c) below the filling device in the sterile filling space. A sterile barrier covers the filler opening of the tube in the mold from formation thereof to filling of the tube in the sterile filling space. A media deliverer 36 is coupled to the sterile barrier, and conveys sterile medium in a direction of the filler opening.

By performing the method and forming the device in this manner, sterile media flows from the sterile barrier in the direction of the filler opening to avoid contamination of the formed

container. This method step and structure proactively deals with the problem of contamination, and involves significantly more than merely use of a heated sterile barrier.

Claims 1 and 5-10 stand under 35 U.S.C. §102 rejected as being anticipated by DE 100 63 282 to Hansen et al. The Hansen patent, cited for allegedly disclosing an apparatus and method for forming, filling and sealing a plastic tube into a filled container, where the tube filler opening is covered by a sterile barrier 26 from the time of its formation to the filling of the respective container. The heating of the sterile barrier 23 is alleged to heat the surrounding air, which heated air is viewed as a sterile medium moved in the direction of the filler opening in which the sterile barrier 23 forms a delivery device. The subject matter claims 5-8 is also alleged to be disclosed in a prior German Hansen patent.

Claims 2-4 and 11 stand rejected under 35 U.S.C. §103 as being unpatentable over the Hansen German patent in view of Pub. U.S. Appl. US2002/0159915 to Zelina. The Zelina publication is cited for the use of hydrogen peroxide as a medium and the use of a suction device in the form of a vacuum device. In support of the rejection, it is contended that it would be obvious to use the hydrogen peroxide and vacuum device of the Zelina publication in the system of the Hansen German patent.

The cited German Hansen patent is interpreted in the Office Action as having a sterile barrier 23 in the form of a heated plate that heats the surrounding air so as to produce allegedly hot air as a sterile medium moved in a direction of a filler element by a media delivery device also provided by the heated plate 23. However, as clearly illustrated in the German Hansen patent, heated plate 23 is located above mold halves 5 of mold 6 and is spaced above the mold 6 by the height of sterile filling space 31. The fill opening 15 formed in the tube by heated cutting

edge 21 is positioned below the sterile filling space, as illustrated in Fig. 4 and described in col. 3, lines 59-62 of the corresponding U.S. Patent No. 7,357,893. To the extent that heated air may be generated by the heated plate 23, such heated air, being of lighter weight than the surrounding ambient air, will move upwardly in a direction away from the fill openings in a manner similar to hot air in a balloon. Any heated air surrounding the Hansen German patent plate 23 will not move downwardly in the direction of the fill openings 15 in the tubes to provide a sterilization effect on the openings of the tubes or containers. In contrast, both the method of claim 12 and the device of claim 24 require conveying a sterile medium in a direction of the filler opening from the sterile barrier by the media delivery device or the media deliverer. Such method step and such structure are not disclosed or rendered obvious by the German Hansen patent, when considered alone or in combination with any of the other cited patent documents.

Accordingly, claims 12 and 24 are patentably distinguishable over the cited patents.

Claims 13-23 and 25-26 being dependent upon claims 12 and 24, respectively, are also allowable for the above reasons. Moreover, these dependent claims recite additional features further distinguishing them over the cited patent document.

Claim 13 is further distinguished by the sterile medium being sterile air, inner gas and/or hydrogen peroxide. Relative to this claim, the Zelina publication is cited. Although this publication discloses the use of hydrogen peroxide, it does not teach its use as being delivered from a movable sterile barrier, as claimed. Thus, the Zelina publication does not render the subject matter of claim 13 obvious.

Claim 14 is further distinguished by the sterile medium being conveyed at a specified over-pressure (i.e., above ambient air pressure). Again, the Zelina publication is cited for such

overpressure but is deficit in failing to disclose an overpressure being emanated from a movable sterile barrier, as claimed.

Claims 15 and 16 are distinguished by non-viable particles being exhausted by a suction device, or particularly a vacuum device (claim 16). Relative to this feature, the Zelina vacuum pump 112 is cited. However, such vacuum pump does not operate in conjunction with the dispensing of sterile media from a sterile barrier.

Claim 17 is further distinguished by the sterile barrier being a plate-shaped cover element that provides the filler opening with sterile media until the container is filled below a sterile filling space. As noted above, the plate 23 of the German Hansen patent does not provide the tube filler opening with a sterile medium, as claimed, since the hot air generated thereby will rise in a direction away from the filter opening.

Claim 18 is further distinguished by the concurrent movement of the cover element and the separating element and the covering of the filler element until the filling of the container.

Claim 19 is further distinguished by the synchronous movement of the parts of the mold with the cover element, as described in connection with the embodiment of Fig. 12. Such embodiment is not disclosed or rendered obvious by the German Hansen patent.

Claim 20 is further distinguished by the container being flushed across the filler opening by the sterile media. No such flushing is provided by the alleged hot air of the German Hansen patent.

Claim 21 is further distinguished by the container being partially filled with the sterile media. Due to the rising of the hot air in the German Hansen patent, no such filling will occur.

Claims 22 and 23 are further distinguished by the specific temperature ranges recited therein.

Claim 25 is further distinguished by the media deliverer comprising outlet ports and at least one inlet port in a plate shaped cover element. No such outlet ports and inlet port are disclosed in the German Hansen patent.

Claim 25 is further distinguished by a suction frame that can enclose the cover element in one position. No such combination is disclosed or rendered by the German Hansen and/or the Zelina publication.

In view of the foregoing, claims 12-26 are allowable. Prompt and favorable action is solicited.

Respectfully submitted,

  
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